

### REMARKS

Claims 13-18, 28, and 33-72 are pending in the application. Claims 13-18, 28, 33-40 and 63-72 are withdrawn from consideration. Claims 48-54 are allowed. Claims 46, and 55-62 are rejected. Claims 41-45 and 47 are objected to. Claims 41, 46 and 62 have been amended to delete reference to the non-elected inventions, and to better clarify what Applicants regard as the invention. Claims 47 and 55-61 have been canceled without prejudice or disclaimer. No new matter has been added by way of this amendment. Thus, as a result of the foregoing amendment, claims 41-46, 48-54 and 62 remain under examination.

The amended claims are shown above without markings. Attached hereto is a version with markings to show the changes made, captioned "Version with markings to show changes made."

Claims 41-46 are objected to because they are drawn in part to non-elected inventions. Accordingly, the claims have been amended to delete reference to the non-elected inventions. Thus, withdrawal of the objection is respectfully requested.

Claim 47 was objected to as being dependent on a rejected base claim. Request has been made to cancel claim 47 without prejudice or disclaimer.

Claims 46 and 62 were rejected under 35 U.S.C. 112, second paragraph as being indefinite. Furthermore, claim 46 was also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims have been amended to better clarify what Applicants regard as the invention. Support for the amendments can be found on page 35, line 16-17, and on page 32, lines 11-19. Thus, withdrawal of the rejections is respectfully requested.

Claim 62 is rejected under 35 U.S.C. §102(e) as being anticipated by Briles et al. (U.S. Patent No. 6,500,613). Claim 62 is also rejected under 35 U.S.C. §102(a) as being anticipated by Briles et al. (WO97/09994). Applicants have provided arguments and further evidence and support for a right of priority to Applicants own provisional application, filed on May 1, 1996, (as related to SEQ ID NO: 20), thus obviating the Examiner's rejection under 35 U.S.C. 102(e) and 102(a) of the Briles et al. reference

(U.S. Patent No. 6,500,613), which was filed on September 16, 1996. Furthermore, Applicants have amended claim 62 to delete reference to SEQ ID NO: 20, thus obviating the Examiner's rejection. Thus, withdrawal of the rejections is respectfully requested.

Claims 55-61 were rejected under 35 U.S.C. 103(a) as being unpatentable over Briles et al. (U.S. Patent No. 6,500,613 or WO97/09994). Applicants have canceled claims 55-61 without prejudice or disclaimer, thus obviating the Examiner's rejection. Thus, Applicants respectfully request withdrawal of this rejection.

The Examiner alleges that Applicant is denied the benefit of priority to provisional application 60/016,632 for claims 41-62. Applicants have provided evidence and support for the subject matter of claims 41-46 and 62 in the provisional application, thus obviating in part the Examiner's rejection of the claim for priority to the provisional application. Thus, Applicants respectfully request reconsideration of the earlier priority date as related to the subject matter of claims 41-46 and 62 in the instant application.

#### ***Claim Objections***

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have canceled the claim without prejudice or disclaimer, thus obviating the Examiner's objection. Thus, withdrawal of this objection is respectfully requested.

Claims 41-46 were also objected to as being drawn to subject matter which was not elected for examination. Applicants respectfully traverse the Examiner's objection, and have amended the claims to correct a typographical error by deleting reference to SEQ ID NO: 6 which was inadvertently included in the claim rather than SEQ ID NO: 9. Applicants respectfully point out to the Examiner that SEQ ID NO: 9 was included with the sequences of Group VII as originally elected in response to the restriction requirement.

#### ***Claim Rejections under 35 U.S.C. §112***

The Examiner has rejected Claim 46 under 35 U.S.C. 112, second paragraph as being indefinite. Furthermore, the Examiner has rejected claim 46 under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification

in such a way as to reasonably convey to one skilled in the art that the inventor(s) at the time the application was filed had possession of the claimed invention.

Applicants respectfully traverse the Examiner's rejections and have amended the claim to better clarify what Applicants regard as the invention. Support for the amendment can be found on page 35, line 16-17, and on page 32, lines 11-19. In light of the foregoing amendment, Applicants respectfully request withdrawal of the rejection.

The Examiner has rejected claim 62 under 35 U.S.C. 112, second paragraph as being indefinite. Applicants respectfully traverse the Examiner's rejection, and have amended the claim to better clarify what Applicants regard as the invention. Support for the claim amendment can be found in the specification on page 32, lines 11-19, wherein "substantially homologous" is defined as noted below:

"Two DNA sequences are "substantially homologous" when at least about 75% (preferably at least about 80%, and most preferably at least about 90 or 95%) of the nucleotides match over the defined length of the DNA sequences. Sequences that are substantially homologous can be identified by comparing the sequences using standard software available in sequence data banks, or in a Southern hybridization experiment under, for example, stringent conditions as defined for that particular system. Defining appropriate hybridization conditions is within the skill of the art. See, e.g., Maniatis et al., *supra*; DNA Cloning, Vols. I & II, *supra*; Nucleic Acid Hybridization, *supra*."

Furthermore, support for the difference between SEQ ID NO: 24, as now claimed in claim 62, and Figure 25 in the Briles et al. reference is found in the sequence alignment attached herein for the Examiner's convenience. "Substantially homologous", as defined herein, refers to two DNA sequences whose nucleotides match over **at least** 75% of a defined length. The sequence alignment, as provided herein, notes a percent identity of 66.1% and a divergence of 45.3%, between SEQ ID NO: 24 and Figure 25 of the Briles reference, thus falling outside the range of "substantially homologous".

Withdrawal of the rejection is thus respectfully requested.

#### ***Priority***

The Examiner alleges that Applicants are denied benefit of priority to the

provisional application U.S. Serial No. 60/016,632, because it fails to contain an adequate written description of the nucleic acids claimed. Applicants respectfully point out that the subject matter of claims 41-46 can be found in U.S. Serial No. 60/016,632 on page 8, lines 1-27, page 9, lines 8-10, page 10, lines 9-15 and lines 22-29, page 12, lines 8-10 and particularly pages 74-75, as SEQ ID NO: 1 and page 77, as SEQ ID NO: 9. Applicants have provided evidence and support for the subject matter of claim 41-46 in the provisional application, thus obviating in part the Examiner's rejection of the claim for priority to the provisional application. Thus, Applicants respectfully request reconsideration of the earlier priority date as related to the subject matter of claims 41-46 in the instant application

#### ***Claim Rejections under 35 U.S.C. §102***

Claim 62 was rejected under 35 U.S.C. §102(e) as being anticipated by Briles et al (U.S. Patent No. 6,500,613). Furthermore, the Examiner has rejected claim 62 under 35 U.S.C. §102(a) as being anticipated by Briles et al. WO97/09994. The Examiner alleges that Briles et al. disclose a nucleic acid sequence in Figure 25, which is 97% identical to SEQ ID NO: 20. Applicants respectfully traverse the Examiner's rejection and have deleted SEQ ID NO: 20 from claim 62, thus obviating the Examiner's rejection. Thus, withdrawal of the rejection is respectfully requested.

#### ***Claim Rejections under 35 U.S.C. §103***

Claims 55-61 are rejected under 35 U.S.C. §103(a) as being unpatentable over Briles et al. (U.S. Patent No. 6,500,613 or WO97/09994).

Applicants respectfully traverse the Examiner's rejection and have canceled claims 55-61 without prejudice or disclaimer. In light of the foregoing, withdrawal of the rejection is respectfully requested.

#### ***Fees***

A check in the amount of \$410 is enclosed to cover the petition for a two month extension of time. No other fees are believed to be necessitated by this amendment.

However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

***Conclusion***

Applicants believe that the foregoing amendments to the claims place the application in condition for allowance. Withdrawal of the rejections and objections is respectfully requested. If a discussion with the undersigned will be of assistance in resolving any remaining issues, the Examiner is invited to telephone the undersigned at (201) 487-5800, ext. 118, to effect a resolution.

Respectfully submitted,



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Enclosures: Sequence alignment



VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The following amended claims 41, 46 and 62 shall replace the pending claims having the same claim numbers:

41. (Amended) An isolated nucleic acid encoding a streptococcal choline binding protein; wherein the protein is expressed by *Streptococcus pneumoniae* and has the following characteristics:

- a) choline-binding activity;
- b) elution from a chromatographic column in the presence of about 10% choline;
- c) being reactive with sera from patients infected or recovering from infection with the bacteria;
- d) being labeled by fluorescein isothiocyanate (FITC) without requiring streptococcal lysis; and
- e) comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1, and SEQ ID NO: [6] 9.

46. (Amended) An oligonucleotide capable of screening for a nucleic acid encoding a streptococcal choline binding protein, wherein the nucleotide is capable of hybridizing with the nucleic acid encoding an amino acid of SEQ ID NO: 1 or SEQ ID NO: 9 [prepared from the nucleic acid of Claim 41].

62. (Amended) A nucleic acid that [hybridizes] is substantially homologous to the nucleotide sequence of [SEQ ID:20 and/or] SEQ ID NO:24 [under highly stringent hybridization conditions].